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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|---|-------------|-----------------------|-------------------------------|------------------|
| 10/002,521  | 11/01/2001  | Timothy Samuel Girton | 760-35 CIP                    | 6660             |
| 7590  | 12/02/2005  |                       | EXAMINER<br>PATTERSON, MARC A |                  |
| Daniel A. Scola, Jr.<br>HOFFMANN & BARON, LLP<br>6900 Jericho Turnpike<br>Syosset, NY 11791 |             |                       | ART UNIT<br>1772              | PAPER NUMBER     |

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/002,521

Applicant(s)

GIRTON ET AL.

Examiner

Marc A. Patterson

Art Unit

1772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 21, 22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 21, 22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2/4/02, 8/19/02.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 26 is rejected under 35 U.S.C. 102(b) as being anticipated by Yen et al (U.S. Patent No. 4,906,377) as evidenced by Verona et al (U.S. Patent No 5,776,185).

With regard to Claim 26, Yen et al disclose a PTFE (comprising polytetrafluoroethylene; column 3, lines 11 – 16) which is extruded (column 3, lines 40 – 44) having a polymeric component which is incompatible with the PTFE in the form of a liquid (an oligomer, therefore a liquid, which is phase separated, therefore comprising discrete domains which are incompatible; column 4, lines 14 – 15) which is extractable therefrom to create pores in the resin (the solvent of the oligomer is extracted and the resulting polymer is microporous; column 2, lines 41 – 45). Yen et al do not disclose a node and fibril structure or expansion, and a non – expanded tube having PTFE resin having no node and fibril structure is therefore disclosed by Yen et al. Yen et al disclose pores which have a diameter of 5 microns (column 4, lines 14 – 16) and therefore permit tissue ingrowth. Yen et al do not disclose an extrudate which permits tissue growth upon implantation, but Verona et al disclose that PTFE is biocompatible (column 4, lines 25 – 27); the property of permitting tissue growth upon implantation is therefore inherent to Yen et al.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Yen et al (U.S. Patent No. 4,906,377).

With regard to Claim 1, Cabasso et al disclose a medical device (used for slow release of drugs; column 6, lines 7 – 8) PTFE (column 5, line 11) which is implantable (biodegradable; column 6, lines 9 – 10) and comprises a PTFE matrix (polytetrafluoroethylene; column 5, lines 5 – 11) having therein a polymeric material (water soluble polymer; column 4, lines 59 – 60) which is extractable upon exposure to dissolving medium to create pores in the matrix (removal of the components yields a beehive morphology comprising holes which are pores; column 5, lines 60 – 68; column 6, lines 1 – 4) and therefore form discrete domains; the pores have a diameter of 10 micrometers (column 6, lines 7 – 10) and therefore permit tissue growth upon implantation; the extractable polymeric material disclosed by Cabasso et al is enveloped by a crosslinked polymer shell (column 5, lines 60 – 68) and Cabasso et al therefore disclose an interpenetrating network comprising PTFE. Cabasso et al do not disclose a PTFE matrix having a node and fibril structure and do not disclose expansion, and Cabasso et al therefore disclose a non expanded PTFE matrix having no node and fibril structure. The device is a membrane (column 3, lines 54 – 55) and which is made by casting from a solvent (column 2, lines 54 – 58) Cabasso et al fail to disclose a matrix which is extruded into a tube.

Yen et al teach the extrusion of polytetrafluoroethylene (column 3, lines 10 – 15 and lines 43 – 45) combination with casting from a solvent (a melt blend of the polymer and solvent is extruded; column 3, lines 33 – 39) and formation of a tube (rolled onto a core; column 4, lines 12 – 14) in the making of a membrane (column 4, line 37) for the purpose of making a membrane which is suitable for storage (column 4, lines 12 – 14). One of ordinary skill in the art would therefore have recognized the advantage of providing for the extrusion into a tube of Yen et al in Cabasso et al, which comprises polytetrafluoroethylene, depending on the desired suitability for storage of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a matrix which is extruded into a tube in Cabasso et al in order to obtain a membrane which is suitable for storage as taught by Yen et al.

With regard to Claim 21, the polymeric material disclosed by Cabasso et al comprising silicone (polyamino methylsiloxane; column 4, lines 60 – 62).

5. Claims 2 – 3, 22 and 24 – 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabasso et al (U.S. Patent No. 4,951,381) in view of Yen et al (U.S. Patent No. 4,906,377) and further in view of Chuter (U.S. Patent No. 6,293,969)

Cabasso et al and Yen et al disclose a medical device comprising a PTFE membrane comprising extractable polymeric material as discussed above. With regard to Claim 2, Cabasso et al and Yen et al fail to disclose a radially distensible stent positioned axially about the tubular extrudate.

Chuter teaches a PTFE membrane (PTFE membrane material; column 2, lines 49– 53) comprised in first and second stents (first and second stent graft components; column 2, lines 45 – 47) with one stent positioned about the other stent (the stent components are at different levels, one below the other; column 2, lines 28 – 29) for the purpose of obtaining a stent which is biologically inert (column 2, lines 49 – 53). One of ordinary skill in the art would therefore have recognized the advantage of providing for the stent of Chuter in Cabasso et al and Yen et al, which a PTFE membrane, depending on the desired inertness of the end product.

It therefore would have been obvious for one of ordinary skill in the art at the time Applicant's invention was made to have provided for a stent, therefore radially distensible, positioned axially about the tubular extrudate in Cabasso et al and Yen et al in order to obtain a stent which is biologically inert as taught by Chuter.

With regard to Claim 3, the stent disclosed by Chuter is a vascular graft (stent – graft for an artery; column 1, lines 39 – 45).

With regard to Claim 22, the extractable material disclosed by Cabasso et al is particulate (droplets; column 4, lines 50 – 55) and having a particle size of 5 microns (0.1 – 3000 micrometers; column 2, lines 58 – 59).

With regard to Claim 24, Cabasso et al and Yen et al do not disclose a component other than the PTFE and extractable polymeric material; Cabasso et al and Yen et al therefore disclose a device consisting essentially of a PTFE resin and a polymeric component.

With regard to Claim 25, the extractable polymeric material disclosed by Cabasso et al and Yen et al comprises polyvinyl alcohol (column 4, lines 63 – 64).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marc A Patterson whose telephone number is 571-272-1497.

The examiner can normally be reached on Mon - Fri 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Marc Patterson 11/28/05*

Marc A. Patterson, PhD.  
Examiner  
Art Unit 1772